

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

DEY, L.P. and DEY, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 08-372 (JJF)
)	
SEPRACOR INC.,)	
)	
Defendant.)	
)	
)	

**DECLARATION OF SAM V. DESAI IN SUPPORT OF PLAINTIFFS
DEY, L.P. AND DEY, INC.'S BRIEF IN
OPPOSITION TO SEPRACOR'S MOTION TO DISMISS**

I, Sam V. Desai, am a member of the law firm Frommer Lawrence & Haug LLP, counsel for Plaintiffs, Dey, L.P. and Dey, Inc. I make this declaration in support of DEY, L.P.'S AND DEY, INC.'S BRIEF IN OPPOSITION TO SEPRACOR'S MOTION TO DISMISS.

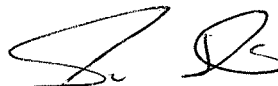
1. Attached as Exhibit 1 is a true and correct copy of a May 1, 2008 Press Release of Sepracor Inc.
2. Attached as Exhibit 2 is a true and accurate copy of Settlement and License Agreement between Sepracor Inc. and Breath Limited filed by Sepracor with the Securities and Exchange Commission on August 8, 2008.
3. Attached as Exhibit 3 is a true and correct copy of the March 7, 2008 Court transcript held before Judge Joseph J. Farnan in the case *Sepracor v. Barr*, C.A. No. 07-438 and the case *Sepracor v. Dey*, C.A. No. 06-113, in the United States District Court for the District of Delaware.

4. Attached as Exhibit 4 is a true and correct copy of COVENANT NOT TO SUE REGARDING U.S. PATENT NO. 6,451,289 dated August 12, 2008.

5. Attached as Exhibit 5 is a true and correct copy of SEPRACOR'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO CONSOLIDATE THE DEY AND BARR CASES dated February 29, 2008.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: September 2, 2008



Sam V. Desai

EXHIBIT 1

**DEY, L.P.'S AND DEY, INC.'S BRIEF IN OPPOSITION TO
SEPRACOR'S MOTION TO DISMISS**

Sepracor - For Investors - Press Release

Press Release

Sepracor Announces Final Settlement of XOPENEX(R) Inhalation Solution Patent Infringement Litigation with Breath Limited

MARLBOROUGH, Mass.--(BUSINESS WIRE)--May 1, 2008--Sepracor Inc. (Nasdaq: SEPR) today announced that it has entered into a Settlement and License Agreement with Breath Limited (Breath), an Arrow Group subsidiary, to resolve the patent litigation involving Sepracor's XOPENEX(R) brand levalbuterol HCl Inhalation Solution products (1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL). The agreement permits Breath to launch generic versions of these XOPENEX Inhalation Solution dosages under terms of an exclusive license commencing on August 20, 2012. Upon launch, Breath would pay Sepracor a double-digit royalty on gross profits generated from the sales of generic versions of these XOPENEX Inhalation Solution dosages. The parties will promptly file a dismissal without prejudice in the United States District Court for the District of Massachusetts that will conclude this litigation.

Sepracor and Breath also contemporaneously entered into a Supply Agreement whereby, effective August 20, 2012, Sepracor will exclusively supply levalbuterol HCl products (1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL) to Breath, under Sepracor's New Drug Application (NDA), for a period of 180 days and on a non-exclusive basis for a period of time thereafter. In addition to the royalties described above, Breath will pay Sepracor on a cost plus margin basis for supply of the levalbuterol HCl products. Both the exclusive license under the Settlement and License Agreement and the exclusive supply obligations under the Supply Agreement could become effective prior to August 20, 2012 if a third party launches a generic version of those dosages of XOPENEX Inhalation Solution or if the parties otherwise agree.

"We are very pleased to have reached a resolution of our dispute with Breath, which allows both parties to avoid the uncertainties and significant expenses related to complex patent litigation," said Adrian Adams, President and Chief Executive Officer of Sepracor Inc. "With this lawsuit behind us, Sepracor can continue to focus on leveraging the many opportunities that lay ahead with respect to our current product portfolio and our growing research and development pipeline, in addition to our efforts directed toward achieving success with the recently launched OMNARIS(TM) Nasal Spray product and the expected launch of ALVESCO(R) Inhalation Aerosol later this year."

"We are very pleased to be able to settle this matter," said Ian McAffer, Managing Director of Breath Limited. "This settlement will provide us with the certainty of being in a position to introduce versions of the XOPENEX Inhalation Solution products on a date certain without the burden of litigation."

The settlement agreement is a final settlement of the Breath litigation. The settlement with Breath does not end all disputes related to generic XOPENEX Inhalation Solution products, as litigation against Dey L.P. and Barr Laboratories, Inc. remains pending. In compliance with U.S. law, the Settlement and License Agreement and Supply Agreement will be submitted to the U.S. Federal Trade Commission and Department of Justice and are subject to their review.

About Sepracor

Sepracor Inc. is a research-based pharmaceutical company dedicated to treating and preventing human disease by discovering, developing and commercializing innovative pharmaceutical products that are directed toward serving unmet medical needs. Sepracor's drug development program has yielded a portfolio of pharmaceutical products and candidates with a focus on respiratory and central nervous system disorders. Currently marketed products include LUNESTA(R) brand eszopiclone,

Sepracor - For Investors - Press Release

XOPENEX(R) brand levalbuterol HCl Inhalation Solution, XOPENEX HFA(R) brand levalbuterol tartrate Inhalation Aerosol, BROVANA(R) brand arformoterol tartrate Inhalation Solution and OMNARIS(TM) brand ciclesonide Nasal Spray. Sepracor's corporate headquarters are located in Marlborough, Massachusetts.

Forward-Looking Statement

This news release contains forward-looking statements that involve risks and uncertainties, including statements with respect to the timing of introduction of generic versions of XOPENEX Inhalation Solution; Sepracor leveraging opportunities with respect to its current product portfolio and its growing research and development pipeline; achieving success with OMNARIS Nasal Spray; and the expected launch of ALVESCO Inhalation Aerosol later this year. Among the factors that could cause actual results to differ materially from those indicated by such forward-looking statements are: Sepracor's ability to fund, and the results of, further clinical trials with respect to products under development; the timing and success of submission, acceptance, and approval of regulatory filings; the scope of Sepracor's trademarks, patents and the patents of others and the success of challenges by others of Sepracor's patents; the clinical benefits and commercial success of the company's products; Sepracor's ability to realize the benefits of its sales force realignment and to expand its sales force capacity to accommodate the launches of OMNARIS Nasal Spray and ALVESCO Inhalation Aerosol; the ability of the company to attract and retain qualified personnel; the ability of the company to successfully collaborate with third parties; the performance of Sepracor's licensees and other collaboration partners; and certain other factors that may affect future operating results that are detailed in Sepracor's annual report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission.

In addition, the statements in this press release represent Sepracor's expectations and beliefs as of the date of this press release. Sepracor anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while Sepracor may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Sepracor's expectations or beliefs as of any date subsequent to the date of this press release.

Lunesta, Xopenex, Xopenex HFA and Brovana are registered trademarks of Sepracor Inc. Omnaris is a trademark and Alvesco is a registered trademark of Nycomed GmbH.

For a copy of this release or any recent release, visit Sepracor's web site at www.sepracor.com.

CONTACT: Sepracor Inc.
David P. Southwell
Chief Financial Officer
or
Investor Relations
Jonae R. Barnes, 508-481-6700
Sr. Vice President

SOURCE: Sepracor Inc.

Sepracor - For Investors - Press Release

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995: Statements in this press release regarding Sepracor Inc.'s business which are not historical facts are "forward-looking statements" that involve risks and uncertainties. For a discussion of such risks and uncertainties, which could cause actual results to differ from those contained in the forward-looking statements, see "Risk Factors" in the Company's Annual Report or Form 10-K for the most recently ended fiscal year.

EXHIBIT 2

**DEY, L.P.'S AND DEY, INC.'S BRIEF IN OPPOSITION TO
SEPRACOR'S MOTION TO DISMISS**

EX-10.4 5 a2187119zex-10_4.htm EXHIBIT 10.4

QuickLinks -- Click here to rapidly navigate through this document

Exhibit 10.4

Confidential Materials omitted and filed separately with the Securities and Exchange Commission. Asterisks denote omissions.

SETTLEMENT AND LICENSE AGREEMENT

This SETTLEMENT AND LICENSE AGREEMENT (this "*Agreement*") is made and effective as of April 30, 2008 (the "Effective Date"), by and between Sepracor Inc., a Delaware corporation having its principal place of business at 84 Waterford Drive, Marlborough, MA 10752 ("*Sepracor*"), and Breath Limited, a United Kingdom corporation having its registered address at 930 High Road, London, N12 9RT, United Kingdom ("*Breath Limited*") (each a "*Party*" and collectively, the "*Parties*").

RECITALS

WHEREAS, Sepracor and Breath Limited are parties to the patent infringement litigation captioned, *Sepracor Inc. v. Breath Limited*, Civil Action No. 06-10043 filed on January 13, 2006, pending in the United States District Court for the District of Massachusetts before the Honorable Douglas P. Woodlock (the "*Litigation*");

WHEREAS, Sepracor currently manufactures and markets the Xopenex® brand (levalbuterol hydrochloride) inhalation solutions products (the "*Sepracor Products*");

WHEREAS, Breath Limited filed Abbreviated New Drug Application No. 77-756 (the "*ANDA*") with the United States Food and Drug Administration (the "*FDA*") containing a certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("*Breath's p(IV) certification*") regarding U.S. Patent Nos. 5,362,755; 5,547,994; 5,760,090; 5,844,002; 6,083,993; and 6,451,289 owned by Sepracor (the "*Patents-in-Suit*") and seeking approval to market generic versions of certain levalbuterol hydrochloride inhalation solution products ("*Breath's ANDA Product*");

WHEREAS, Sepracor has alleged that the filing of the ANDA by Breath Limited containing Breath's p(IV) certification is an act of infringement of the Sepracor Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A);

WHEREAS, in response to Breath Limited's p(IV) certification, Sepracor commenced the Litigation;

WHEREAS, Sepracor has asserted in the Litigation that Breath Limited's ANDA Product would infringe certain claims of the Sepracor Patents-in-Suit;

WHEREAS, the Parties wish to fully and finally settle the Litigation and all patent issues concerning Breath's ANDA Product, upon the terms and subject to the conditions set forth below;

WHEREAS, settlement of the Litigation will help both Sepracor and Breath Limited avoid the substantial costs, uncertainty and risk involved with prolonged patent-infringement litigation, trial and appeal;

WHEREAS, settlement of the Litigation will permit both Sepracor and Breath Limited to save substantial litigation costs, as well as adhere to the judicially recognized public policy favoring the settlement of litigation whenever possible;

WHEREAS, settlement of the Litigation will permit the management of both Sepracor and Breath Limited to refocus on running their respective companies rather than devoting substantial time and resources to the Litigation;

WHEREAS, pursuant to the terms of this Agreement, Breath will have the right to enter the market for the Sepracor Products in 1.25 mg/ 3 ml, 0.63 mg/ 3 ml, and 0.31 mg/ 3 ml strengths pursuant to the ANDA at least 8 years prior to the expiration of the last to expire of the Sepracor Patents-in-Suit in the Territory, thereby benefiting consumers by permitting generic entry that may not have occurred if the Litigation were allowed to proceed;

WHEREAS, the public will benefit significantly from this final settlement as it saves judicial resources and creates certainty for Sepracor and Breath Limited that will encourage the development, investment and marketing of levalbuterol hydrochloride inhalation solution products and other pharmaceutical products;

WHEREAS, by reducing litigation expenses, this Agreement allows saved money to be spent on marketing and further drug development, including development of Xopenex® (levalbuterol hydrochloride) inhalation solutions product, allowing the products to reach a larger group of patients and thus improving lives;

WHEREAS, money saved by settling the Litigation can now be invested by Sepracor and Breath Limited into research and development, thereby benefiting consumers by identifying new uses for current drugs, as well as furthering the creation of new proprietary medications; and

WHEREAS, the Parties are concurrently entering into that certain Supply Agreement, pursuant to which Sepracor shall supply Breath with levalbuterol hydrochloride product manufactured pursuant to Sepracor's NDA No. 02-0837, attached as "Attachment B" (the "*Supply Agreement*").

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

Section 1.1. *Certain Defined Terms.* The following terms, when used with initial capital letters shall have the meanings set forth below:

"*Affiliate*" means any entity controlling, controlled by or under common control with a Party, but only as long as such control continues, where "*control*" means: (i) the ownership of at least fifty percent (50%) of the equity or beneficial interest of such entity, or the right to vote for or appoint a majority of the board of directors or other governing body of such entity; or (ii) the power to directly or indirectly direct or cause the direction of the management and policies of such entity by any means whatsoever.

"*Breath*" means Breath Limited and its Affiliates, including but not limited to Cobalt Laboratories Inc.

"*Fully Loaded Manufacturing Cost*" shall mean, with respect to each Licensed Product, a Party's internal and external costs, determined in accordance with International Financial Reporting Standards, as consistently applied by such Party in accordance with its past practice and in the ordinary course of its business for products other than Licensed Products, incurred in manufacturing, acquiring raw materials, including active pharmaceutical ingredient ("API"), excipients and other materials consumed in the manufacture of Licensed Products including all taxes related thereto, packaging, insuring, transporting and/or storing such Licensed Product (including product testing activities relating to quality assurance, quality control and regulatory compliance), and reasonably allocated administrative and overhead expenses associated with the Licensed Product, in each case to the extent related and allocable to the Licensed Product.

"*Gross Profit*" means Net Sales less Fully Loaded Manufacturing Cost.

"*Licensed Products*" means Breath's ANDA Product approved by the FDA for sale pursuant to the ANDA, as existing on the Effective Date.

"*Losses*" means all pending and potential claims, demands, all manner of actions, causes of action, suits, debts, liabilities, losses, damages, attorneys' fees, costs, expenses, judgments, settlements, interest,

punitive damages and other damages or costs of whatever nature, whether known or unknown, pending or future, certain or contingent.

"*Net Sales*" means gross sales of Licensed Products in the Territory less the following deductions:

- (a) sales and excise taxes, duties, and any other governmental charges imposed upon the production, importation, use or sale of Licensed Products, if and to the extent included on the invoice that Breath provides to its customers;
- (b) trade, quantity, cash and other discounts allowed on Licensed Products to wholesalers or other Third Parties to whom the Licensed Products are sold and shipped directly, if and to the extent included on the invoice that Breath provides to its customers;
- (c) provisions for actual or expected allowances or credits to customers on account of rejection or return of Licensed Products or on account of price reductions for a Licensed Products;
- (d) rebates, charge-backs and other price reduction programs for Licensed Products granted to managed care entities and pharmaceutical benefit management service entities (if Breath chooses to contract one or more of the Licensed Products together with another Breath product with composite rebates or chargebacks, then rebates and or chargebacks for the affected Licensed Product will be recalculated based on the then-average rebate or chargeback of the Licensed Product to the applicable customer category as if such Licensed Product is contracted independently of any other Breath product); and
- (e) actual write-offs of uncollectible customer accounts for previously recorded sales.

in each case determined and applied consistently in accordance with Breath's commercial and accounting policies and practices consistently applied in a manner consistent with GAAP.

"*Person*" means any individual, firm, corporation, partnership, limited liability company, trust, joint venture, governmental authority, or other entity or organization.

"*Proceeding*" means any administrative, judicial or legislative action, audit, litigation, investigation, suit or other proceeding in any tribunal.

"*Sepracor Patents*" means the "Patents-in-Suit" and additionally includes any other patent that Sepracor owns or will own, in whole or in part, that is, or could alleged to be, infringed by any of Breath's Licensed Products.

"*Territory*" means the United States of America and its territories and possessions, including the Commonwealth of Puerto Rico and the District of Columbia.

"*Third Party*" means any Person other than Sepracor and Breath.

ARTICLE 2 SETTLEMENT AND RELEASE

Section 2.1. *Mutual Release.* Upon the terms and subject to the conditions of this Agreement, each Party, on behalf of itself and its Affiliates hereby releases, acquits and forever discharges the other Party and its Affiliates, and their respective directors, officers, employees, agents, representatives, heirs, assigns, predecessors and successors ("*Related Parties*") from any and all Losses arising out of, derived from, predicated upon or relating to infringement of the Sepracor Patents by the Licensed Products, and the actions underlying the Litigation. Notwithstanding the foregoing, nothing in this Agreement shall prevent or impair the right of either Party to bring a Proceeding in court or any other forum for breach of this Agreement (including, without limitation, any claim for infringement of any intellectual property based upon activities that are not the subject of the license granted hereunder) or any representation, warranty or covenant herein.

Section 2.2. *Dismissal of Litigation.* The Parties agree to the entry of a Dismissal Without Prejudice of all claims, counterclaims, and affirmative defenses in the Litigation. To effectuate this provision, within 3 business days following execution of this Agreement, the Parties shall cause the Dismissal Without Prejudice attached hereto as Attachment A (each Party acknowledging that the approval of the court is required in order to make such Dismissal Without Prejudice effective) to be filed with the United States District Court for the District of Massachusetts and shall take all other necessary actions to obtain the settlement and dismissal of the Litigation. Each Party shall bear its own costs and expenses in connection with the foregoing.

Section 2.3. *Mutual Agreements.* Each Party acknowledges and agrees that:

(a) It may have sustained Losses that are presently unknown and unsuspected, and that such Losses might give rise to Losses in the future. Nevertheless, each Party acknowledges and agrees that this Agreement has been negotiated and agreed upon, notwithstanding the existence of such possible Losses, all of which have been hereby released under Section 2.1 hereof.

(b) If any fact relating to this Agreement or the Litigation and now believed to be true is found hereafter to be other than, or different from, that which is now believed, each Party expressly assumes the risk of such difference in fact and agrees that this Agreement shall be, and will remain, effective notwithstanding any such difference in fact, subject to each Party's right to bring a Proceeding for a breach of any representation, warranty or covenant herein.

(c) This Agreement may be pleaded as a full and complete defense to, and used as a basis for injunction against, any Proceeding that may be instituted, prosecuted or attempted in breach hereof.

ARTICLE 3 LICENSE

Section 3.1. *License Grant.* Effective as of August 20, 2012, or as modified in accordance with Section 3.6 (the "License Effective Date"), Sepracor hereby grants to Breath a license under the Sepracor Patents, including any continuations, divisions, reissues or reexaminations thereof, without the right to grant sublicenses, to make, have made, use, promote, offer to sell, sell, import, or otherwise dispose of Licensed Products in the Territory. The license granted hereunder shall be exclusive as to any other levalbuterol hydrochloride product marketed as a generic equivalent of Xopenex® brand products covered by Sepracor NDA No. 02-0837 (and any supplements or amendments thereto) for a period of 180 days (the "Exclusivity Period") from the License Effective Date. Following the Exclusivity Period, the license granted to Breath hereunder shall become non-exclusive and Sepracor shall have the right to grant licenses to Third Parties under the Sepracor Patents.

Section 3.2. *Commercial Sales Prior to License Effective Date.* Without limiting the rights of Breath under the Supply Agreement, Breath shall not distribute, offer to sell, sell or sell in the Territory any Licensed Products prior to the License Effective Date. Breath agrees that any breach by Breath or its Related Parties of this Section 3.2 shall cause irreparable harm to Sepracor, and Breath and its and Related Parties consents irrevocably and unconditionally to specific performance, or immediate entry of a temporary restraining order, preliminary injunction, and permanent injunction, to enforce this Section 3.2. Notwithstanding anything to the contrary, Breath and its Related Parties consents irrevocably and unconditionally to personal jurisdiction and venue in the United States District Court for the District of Massachusetts for the purpose of enforcing this Section 3.2. Notwithstanding the foregoing, Breath shall have the right and license under the Sepracor Patents, including any continuations, divisions, reissues or reexaminations thereof, to make, have made and import Licensed Products in the Territory sufficiently in advance of a Licensed Product launch so as to have sufficient quantities of inventory of such product for such launch.

Section 3.3. *Breath's Covenant Not to Assist Challenges to the Licensed Patents.* Except to the extent required by law or order of a court or administrative agency of competent jurisdiction, Breath shall not, and shall cause its Affiliates, Related Parties and their respective counsel who have advised or represented Breath in connection with the Litigation not to, assist, encourage, finance, or otherwise provide any information to any Third Party attacking or who may attack the validity or enforceability of, or assert the noninfringement of, any of the Sepracor Patents.

Section 3.4. *Reservation of Rights.* All rights not expressly granted to Breath hereunder or in the Supply Agreement are expressly reserved to Sepracor, and Sepracor has no obligation to make available any intellectual property rights or to take any other actions other than as expressly set forth herein. Without limiting the terms of the Supply Agreement, nothing in this Agreement shall be construed as granting Breath any rights: (a) with respect to any Licensed Products outside the Territory; (b) with respect to any product other than Licensed Products; or (c) to make, have made, use, offer to sell, sell, import, or otherwise dispose of any generic version of any Sepracor product covered by Sepracor NDA No. 02-0837 or Sepracor Patents at any time prior to the License Effective Date.

Section 3.5. *No Other Limitation.* Nothing in this Agreement is intended to prevent or restrict Breath from making, having made, using, promoting, marketing, distributing, offering for sale, selling, or importing any product, the importation, manufacture, use, offering for sale or selling of which would not infringe the Sepracor Patents under 35 U.S.C. § 271(e)(1).

Section 3.6. *Acceleration of License Effective Date.* Upon the occurrence of a Third Party commercial launch of any particular strength of a generic version of levalbuterol hydrochloride solution products ("The Launch Date") pursuant to an ANDA, the License Effective Date for only that particular strength of the Licensed Products shall be accelerated to that Launch Date. In addition, the parties may in the future mutually agree to accelerate the License Effective Date. It is understood and agreed that, if the Parties anticipate a Third Party commercial launch, Breath may take such action as is reasonably necessary, including manufacture and stock an inventory of Licensed Products, so as to be prepared to launch Licensed Products on the accelerated License Effective Date.

ARTICLE 4 ROYALTIES

Section 4.1. *Royalty.* During the period commencing on the License Effective Date and ending on the later of (i) expiration of the Exclusivity Period, or (ii) the date a Third Party has commenced a commercial launch of a generic levalbuterol product pursuant to an ANDA, Breath shall pay Sepracor a royalty of **[**]** percent (**[**]**%) of Breath's Gross Profit for sales of any Licensed Products. Following such period, Breath shall pay Sepracor a royalty of **[**]** percent (**[**]**%) of Breath's Gross Profit for sales of the Licensed Products. The license granted hereunder shall become fully paid-up and royalty free upon the earlier of (i) the date of the expiration of the last to expire of the Sepracor Patents, or (ii) the date on which a court enters a final decision that is no longer subject to appeal holding that each of the unexpired patent claims included in the Sepracor Patents that were asserted against Breath in the Litigation is invalid, unenforceable or not infringed by a product substantially similar to Breath's ANDA Product.

Section 4.2. *Royalty Payments.* Royalties payable by Breath to Sepracor hereunder shall be determined and paid on a calendar quarterly basis. Within thirty (30) days following the end of each calendar quarter in which royalties are payable hereunder, Breath shall provide Sepracor with (i) a written statement of its Net Sales and Gross Profit for such calendar quarter and the royalties payable hereunder for such quarter, and (ii) payment of the royalties then-payable hereunder. Whenever information relating to Licensed Products is reported under this Agreement, such information shall (i) be listed separately by Licensed Product and dose, and in the aggregate, and (ii) include a breakdown of gross sales of Licensed Products and applicable deductions therefrom.

Section 4.3. *Currency.* All payments under this Agreement shall be in U.S. dollars in immediately available funds, and, unless instructed otherwise by Sepracor, shall be made via wire transfer to an account designated from time to time by Sepracor.

Section 4.4. *Taxes.* Unless otherwise required by law, each Party shall be responsible for paying and reporting all of its own taxes and fees, including without limitation income taxes, payroll taxes, franchise taxes and all taxes and fees in connection with this Agreement.

Section 4.5. *True-Up.* In the event Breath issues any allowances or credits or takes any write-offs related to its recorded Gross Profit on Licensed Products in the Territory, the amount of any applicable underpayment or overpayment will be added or subtracted, as appropriate, to or from the next royalty payment in accordance with this ARTICLE 4 or, if no further royalty payments are due, by payment to the Party owed such adjustment within thirty (30) days after identification of such adjustment.

Section 4.6. *Audit.* Breath shall keep complete and accurate records of Net Sales and Gross Profit on Licensed Products and shall retain such records for a period of at least [**] from the date of the sales reported therein. Sepracor shall have the right, through an independent certified public accountant reasonably acceptable to Breath, upon execution of a confidentiality agreement, to examine such records during regular business hours, in a manner that does not unreasonably interfere with ongoing operations, upon reasonable written notice for so long as any royalties are payable hereunder for Licensed Product sold in the Territory and for [**] thereafter, *provided, however*, that such examination shall not take place more often than [**] per year. Any adjustments required as a result of overpayments or underpayments identified through Sepracor's exercise of audit rights shall be made by subtracting or adding, as appropriate, amounts from or to the next royalty payment in accordance with this ARTICLE 4 or, if no further royalty payments are due, by payment to the Party owed such adjustment within thirty (30) days after identification of such adjustment. Sepracor shall bear the full cost and expense of the audit unless such audit correctly discloses that the discrepancy for the year differs by more than [**] percent ([**]%) from the amount the accountant determines is correct, in such case Breath shall pay the reasonable fees and expenses charged by the accountant. In addition, Breath shall pay interest from the original date due until payment on the amount of the underpayment at a rate equal to the average one-year London Inter-Bank Offering Rate for the United States dollar as reported from time to time in the Wall Street Journal (or, if such rate is not regularly published, as published in such source as the Parties agree) and calculated from the date due until the payment date. In the event that a Party disputes an invoice or other payment obligation under this Agreement, such Party shall timely pay the amount of the invoice or other payment obligation that is not in dispute, and the Parties shall resolve such dispute in accordance with Section 7.2.

**ARTICLE 5
REPRESENTATIONS AND WARRANTIES**

Section 5.1. *Mutual Representations.* Each Party hereby represents and warrants to the other Party as follows:

(a) *Due Authorization.* Such Party is a corporation duly incorporated and in good standing as of the Effective Date, and the execution, delivery and performance of this Agreement by such Party have been duly authorized by all necessary action on the part of such Party.

(b) *Due Execution.* This Agreement has been duly executed and delivered by such Party and, with due authorization, execution and delivery by the other Party, constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms.

(c) *No Conflict.* Such Party's execution, delivery and performance of this Agreement do not: (i) violate, conflict with or result in the breach of any provision of the charter or by-laws (or similar organizational documents) of the Party; (ii) conflict with or violate any law or governmental order applicable to the Party or any of its assets, properties or businesses; or (iii) conflict with, result in any breach of, constitute a default (or event which with the giving of notice or lapse of time, or both, would become a default) under, require any consent under, or give to others any rights of termination, amendment, acceleration, suspension, revocation or cancellation of any note, bond, mortgage or indenture, contract, agreement, lease, sublease, license, permit, franchise or other instrument or arrangement to which it is a party.

Section 5.2. *Sepracor Representations and Warranties.* Sepracor represents and warrants to Breath that, as of the Effective Date, Sepracor (i) has the right to grant to Breath the licenses granted hereunder with respect to the Sepracor Patents, (ii) has the right to settle the Litigation, and (iii) does not license from a Third Party any patents that would preclude Breath from making, using, selling, offering for sale or importing Licensed Products in the Territory.

Section 5.3. *Breath Representations and Warranties.* Breath represents and warrants to Sepracor that (i) Breath Limited owns all right, title and interest in, to and under the ANDA, and Breath has not granted or assigned to any Third Party, directly or indirectly, any rights under or to the ANDA or Breath's ANDA Product, (ii) Breath will not transfer ownership, in whole or in part, of said ANDA, except to an Affiliate of Breath or to a successor to all or substantially all of the business to which this Agreement pertains, until the expiration of the License granted herein, (iii) to the best of Breath's knowledge and belief, it is the sole first entity to file a "substantially complete application" as defined in 21 U.S.C. § 355(j)(5)(B)(iv)(cc) with a paragraph IV certification seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic levalbuterol hydrochloride inhalation solutions in 1.25 mg/3 ml, 0.63 mg/ 3ml, and 0.31 mg/ 3 ml dosage products, and Breath has obtained final approval with respect to these strengths, (iv) Breath is not aware of the occurrence of any forfeiture event as defined in 21 U.S.C. § 355(j)(5)(D)(i), and Breath has received no communication from the FDA informing Breath that it believes that such forfeiture event has occurred, (v) the FDA granted tentative approval of Breath's ANDA within 30 months after the date on which Breath filed the ANDA, (vi) Breath has not amended or withdrawn its paragraph IV certification with respect to any of the Sepracor Patents, (vii) Breath has not withdrawn its ANDA, (viii) Breath has not entered into an agreement concerning levalbuterol hydrochloride with another party that has filed an ANDA seeking to market generic versions of levalbuterol hydrochloride, including but not limited to Barr Laboratories, Inc., Dey, Inc., Dey, L.P., and Watson Laboratories, Inc., (ix) Breath has the right to settle the Litigation, and (x) [**].

Section 5.4. *Disclaimer.* EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES, EXPRESS OR

IMPLIED, EITHER IN FACT OR BY OPERATION OF APPLICABLE LAW, AND EACH PARTY HEREBY EXPRESSLY DISCLAIMS SUCH WARRANTIES.

ARTICLE 6 INDEMNIFICATION

Section 6.1. *Sepracor Indemnification.* Sepracor shall indemnify and hold harmless Breath and its Related Parties from and against any claims, actions, demands, suits, causes of action, losses, damages, liabilities, judgments, costs and expenses (including reasonable attorneys' fees) arising out of or related to any breach of Sepracor's representations, warranties and covenants set forth in this Agreement.

Section 6.2. *Breath Indemnification.* Breath shall indemnify and hold harmless Sepracor, its Affiliates, and its Related Parties from and against any claims, actions, demands, suits, causes of action, losses, damages, liabilities, judgments, costs and expenses (including reasonable attorneys' fees) arising out of or related to: (i) any breach of Breath's representations, warranties and covenants set forth in this Agreement, (ii) the design, manufacture, labeling, marketing, sale or use of any Licensed Product, including any product liability claims, (iii) the failure by Breath to comply with any FDA or other governmental requirement with respect to any Licensed Product, and (iv) the infringement or misappropriation of any Third Party patent, copyright, trademark, service mark, trade secret or other intellectual property based on any Licensed Product.

Section 6.3. *Indemnification Procedures.* The obligations to indemnify, defend, and hold harmless set forth in Section 6.1 and Section 6.2 shall be contingent upon the Party seeking indemnification (the "Indemnatee"): (i) notifying the indemnifying Party of a claim, demand or suit within [**] of receipt thereof; *provided, however*, that the Indemnatee's failure or delay in providing such notice shall not relieve the indemnifying Party of its indemnification obligation except to the extent the indemnifying Party is prejudiced thereby; (ii) allowing the indemnifying Party and/or its insurers the right to assume direction and control of the defense of any such claim, demand or suit; (iii) cooperating with the indemnifying Party and/or its insurers in the defense of such claim, demand or suit at the indemnifying Party's expense; and (iv) agreeing not to settle or compromise any claim, demand or suit without prior written authorization of the indemnifying Party. The Indemnatee shall have the right to participate in the defense of any such claim, demand or suit referred to in this Section utilizing attorneys of its choice, at its own expense, *provided, however*, that the indemnifying Party shall have full authority and control to handle any such claim, demand or suit.

ARTICLE 7 MISCELLANEOUS

Section 7.1. *Assignment.* Neither Party hereto may assign any of its rights or obligations under this Agreement, except to an Affiliate or successor to all or substantially all of the business of the Party to which this Agreement pertains, without the prior written consent of the other Party. Either Party may assign this Agreement in connection with a merger, reorganization, change of control or sale of all or substantially all of the applicable business of such Party, in each case, on written notice to the other Party, *provided* that the successor Person agrees in writing to adhere to all of the terms and conditions of this Agreement. Any purported assignment in violation of the foregoing shall be null and void and of no force or effect. No assignment of this Agreement will relieve the assigning Party from any of its obligations hereunder. In the event of a permitted assignment, this Agreement shall be binding upon and inure solely to the benefit of the Parties and their respective successors and permitted assigns.

Section 7.2. *Dispute Resolution.* Any dispute, controversy or claim arising out of or relating to this Agreement (a "Dispute") shall be attempted to be settled by the Parties, in good faith, by submitting each such Dispute to the Chief Executive Officers of each Party by written notice from either Party to the other Party specifying the terms of such Dispute in reasonable detail. Within [**] of

receipt of such notice, the Chief Executive Officers of each Party, or a member of management designated by the respective Chief Executive Officer, shall meet in person (at a mutually agreed upon time and location) or by telephone for the purpose of resolving such Dispute. They will discuss the problems and/or negotiate for a period of up to [**] in an effort to resolve the Dispute or negotiate an acceptable interpretation or revision of the applicable portion of this Agreement mutually agreeable to both Parties, without the necessity of formal procedures relating thereto. If the problem is not resolved within the period set forth above, either Party shall be free to pursue all available remedies, at law or in equity, consistent with the terms of this Agreement. Notwithstanding the foregoing, either Party may apply to a court of competent jurisdiction for a temporary restraining order, preliminary injunction or other equitable relief, where such relief is necessary to protect its interests.

Section 7.3. *Governing Law and Venue.* This Agreement shall be governed by and construed in accordance with the laws of the State of Massachusetts, without giving effect to its conflict of laws principles. The Parties hereby consent to the exclusive jurisdiction of the federal courts located in Massachusetts, and expressly waive any objections or defenses based on lack of personal jurisdiction or venue in connection with any dispute arising out of or relating to this Agreement.

Section 7.4. *Bankruptcy.* All rights and licenses granted under or pursuant to any Section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code (the "*Bankruptcy Code*"), licenses of "intellectual property" as defined under the Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the Bankruptcy Code.

Section 7.5. *Confidentiality.* Sepracor and Breath shall not use or disclose to Third Parties any information received from the other Party or otherwise developed or obtained (including prior to the date hereof or during any period in which the Parties have audit rights pursuant to Section 4.6) by either Party in the performance of activities under this Agreement without first obtaining the written consent of the disclosing Party, except as may be otherwise provided in, or required in order for a Party to exercise its rights or fulfill its obligations under, this Agreement. This confidentiality obligation shall not apply to information that (i) is or becomes a matter of public knowledge (other than by breach of this Agreement by the receiving Party), (ii) is required by law, regulation or order of a court or administrative agency of competent jurisdiction, to be disclosed, (iii) the receiving Party can establish was already known to it or was in its possession at the time of disclosure, (iv) the receiving Party can establish was independently developed by Persons in its employ who had no contact with and were not aware of the content of the confidential information, or (v) is disclosed to the receiving Party by a Third Party having no obligation of confidentiality to the disclosing Party with respect to such information. The Parties shall take reasonable measures to assure that no unauthorized use or disclosure is made by others to whom access to such information is granted.

Section 7.6. *Publicity.* Except as consistent with a press release mutually agreed by the Parties, or other publicly disclosed information concerning this Agreement, no public announcement or other disclosure to Third Parties concerning the existence of or terms of this Agreement shall be made, either directly or indirectly, by either Party, without first obtaining the written approval of the other Party and agreement upon the nature, text and timing of such announcement or disclosure; *provided, however*, either Party shall have the right to make any such public announcement or other disclosure required by law after such Party has provided to the other Party a copy of such announcement or disclosure and an opportunity to comment thereon. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement to the Securities Exchange Commission and any other governmental or regulatory agencies, including requests for confidential treatment of proprietary information of either Party included in any such disclosure. Neither Party shall be required to provide the other Party with any advance notice of any public announcements or other disclosures related to periodic, routine financial reporting unless such announcement or other disclosure will include non-routine information relating to the Licensed Products or this Agreement.

Section 7.7. Cooperation. Subject to confidentiality restrictions that may be reasonably requested, the Parties shall use their respective commercially reasonable efforts to:

(a) Make all required filings with all governmental authorities and obtain all necessary approvals in connection with this Agreement to the extent required under applicable laws. Subject to confidentiality restrictions that may be reasonably requested and to the extent permissible by law, Sepracor and Breath shall make every effort to coordinate and exchange all filings and documents submitted to all government authorities regarding this Agreement;

(b) Cooperate with each other in any review, investigation, inquiry or proceeding regarding the Agreement by any government authority. Subject to such confidentiality restrictions as may be reasonably requested and to the extent permissible by law, Sepracor and Breath will render reasonable assistance as the other may request in connection with this Agreement and coordinate and cooperate with one another in exchanging information, permitting reasonable access to Sepracor's and Breath's documents, officials, and data in connection with any such review, investigation, inquiry or proceeding by any governmental authority;

(c) Promptly inform each other of any material communication made to, or received by such party from any governmental authority regarding this Agreement;

(d) Defend, contest and resist any administrative, judicial or legislative action or proceeding that is instituted (or threatened to be instituted) challenging the transactions contemplated by this Agreement as violative of any applicable law, and have vacated, lifted, reversed or overturned any decree, judgment, injunction or other order (whether temporary, preliminary or permanent) that is in effect and that challenges this Agreement, including, without limitation, by pursuing all reasonable avenues of administrative and judicial appeal;

Without limiting any other provision of this Agreement, take all actions and do all things reasonably necessary or proper (at its own cost and expense), including under applicable law to make effective and further the intent and purposes of the transactions contemplated by this Agreement, including executing any further instruments reasonably requested by the other Party, and to resist and to contest any proposals or efforts to materially alter the terms of the Agreement so as to permit the Parties to fulfill their obligations under and to obtain the full benefits contemplated by the Agreement.

Section 7.8. Government Proceedings. Within ten (10) business days following the Effective Date, and pursuant to current statutory law, the Parties shall file or cause to be filed this Agreement with the U.S. Federal Trade Commission Bureau of Competition ("*FTC*") and the Assistant Attorney General for the Antitrust Division of the U.S. Department of Justice ("*DOJ*") and shall request that the FTC and DOJ treat this Agreement as confidential to the fullest extent permitted under the law.

Section 7.9. Notices. All notices required or permitted under this Agreement must be in writing and must be given by addressing the notice to the address for the recipient set forth below or at such other address as the recipient may specify in writing under this procedure. Notices will be deemed to have been given (a) three (3) business days after deposit in the mail with proper postage for first class

registered or certified mail prepaid, return receipt requested, or (b) one (1) business day after sending by nationally recognized overnight delivery service.

If to Sepracor:

Sepracor Inc.
Attn: Adrian Adams
President and Chief Executive Officer
84 Waterford Drive
Marlborough, MA 01752
Phone: (508) 481-6700
Fax: (508) 357-7492

If to Breath:

Attn: Ian McAffer
Managing Director
Breath Limited
100 Paynesfield Road
Tatsfield
Westerham
Kent TN16 2BQ
United Kingdom.
Phone: +44 1959 542 578
Fax: +44 1959 542 578

With a copy to:

Andrew I. Koven
Executive Vice President, General Counsel
and Corporate Secretary
Sepracor Inc.
84 Waterford Drive
Marlborough, MA 01752
Phone: (508) 357-7307
Fax: (508) 357-7511

With a copy to:

Francis Mifsud
Arrow International Limited
57 St Christopher Street
Valletta, VLT 08, Malta
Phone: +356 2165 3041
Fax: +356 2165 3046

Section 7.10. *Amendment.* This Agreement may not be amended or modified except by an instrument in writing signed by authorized representatives of Sepracor and Breath.

Section 7.11. *No Waiver.* The failure of either Party to enforce at any time for any period the provisions of or any rights deriving from this Agreement shall not be construed to be a waiver of such provisions or rights or the right of such Party thereafter to enforce such provisions.

Section 7.12. *Severability.* If any term or other provision of this Agreement is invalid, illegal or incapable of being enforced by any law or public policy, all other terms and provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any Party.

Section 7.13. *Headings.* The descriptive headings contained in this Agreement are for convenience of reference only and shall not affect in any way the meaning or interpretation of the Agreement.

Section 7.14. *Counterparts.* This Agreement may be executed in one or more counterparts, and by the respective Parties in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same Agreement.

Section 7.15. *Entire Agreement.* This Settlement and License Agreement and the contemporaneously executed Supply Agreement constitute the entire agreement between the Parties with respect to the subject matter hereof, and no oral or written statement that is not expressly set forth in this Settlement and License Agreement or the Supply Agreement may be used to interpret or vary the meaning of the terms and conditions hereof. This Settlement and License Agreement and the Supply Agreement supersede any prior or contemporaneous agreements and understandings, whether written or oral, between the Parties with respect to the subject matter hereof.

Section 7.16. *Third Party Beneficiaries.* Except as expressly provided herein, nothing in this Agreement, either express or implied, is intended to or shall confer upon any third party any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

[Remainder of Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, this Agreement has been executed by the Parties as of the date first written above.

SEPRACOR INC.

BREATH LIMITED

By: /s/ Adrian Adams

By: /s/ Ian Gardner Cameron McAffer

Name: Adrian Adams

Name: Ian Gardner Cameron McAffer

Title: President and Chief Executive Officer

Title: Managing Director

ATTACHMENT A

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

SEPRACOR INC.,

Plaintiff,

v.

C. A. No. 06-10043-DPW

BREATH LIMITED,

Defendant.

DISMISSAL WITHOUT PREJUDICE

Plaintiff Sepracor Inc. ("Sepracor"), and Defendant Breath Limited ("Breath"), having agreed to a settlement of this action, STIPULATE that:

1. The above parties to this Civil Action No. 06-10043 (DPW) (referred to as "the Litigation") wish to settle this dispute.
2. This Court has jurisdiction over the parties and the subject matter of the Litigation.
3. Plaintiff Sepracor owns and/or has the legal title and interest in and to United States Letters Patent Nos. 5,362,755 ("the '755 patent"), 5,547,994 ("the '994 patent"), 5,760,090 ("the '090 patent"), 5,844,002 ("the '002 patent"), 6,083,993 ("the '993 patent"), and 6,451,289 (the '289 patent") (collectively the "Sepracor Patents").
4. In the Litigation, Sepracor alleged that Breath infringed the Sepracor Patents, under 35 U.S.C. § 271(e)(2), by virtue of Breath's submission of Abbreviated New Drug Application No. 77-756 ("Breath's ANDA") to the United States Food and Drug Administration ("FDA") containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), asserting that the Sepracor patents are invalid, unenforceable and/or not infringed.
5. Breath's ANDA containing the paragraph IV certification was submitted to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to engage in the commercial manufacture, use and sale of generic copies of certain Xopenex® (levalbuterol hydrochloride) inhalation solutions in 1.25 mg/3 ml, 0.63 mg/3ml, and 0.31 mg/3 ml dosage products prior to the expiration of the Sepracor patents.
6. In December 2007, the FDA granted tentative approval to Breath's ANDA.
7. Sepracor's filing of the Litigation caused an automatic 30 month stay of the FDA's approval of Breath's ANDA. The thirty-month stay of FDA approval of Breath's ANDA expired on March 7, 2008, and the FDA granted final approval on April 9, 2008.
8. On March 17, 2008, Breath and Sepracor agreed and stipulated to this Court that Breath will provide Sepracor with at least 30 days' notice prior to commencing, or authorizing a third party to commence under Breath's ANDA, the commercial launch of a generic levalbuterol hydrochloride inhalation solution product.
9. Plaintiff and Defendant have reached agreements to settle the Litigation, as set forth in this stipulated Dismissal Without Prejudice and a separate Settlement and License Agreement and Supply Agreement, which are being executed contemporaneously.
10. As a result of the Settlement and License Agreement and the Supply Agreement there will be early, procompetitive generic competition for Xopenex® (levalbuterol hydrochloride) inhalation

A-1

solutions in 1.25 mg/3 ml, 0.63 mg/3ml, and 0.31 mg/3 ml dosage products in the United States, which competition might have been delayed or otherwise might not have occurred or been allowed to continue, had Sepracor prevailed in the Litigation. The settlement has a number of other procompetitive effects. Among other benefits, this settlement allows generic entry of levalbuterol hydrochloride inhalation solutions in 1.25 mg/3 ml, 0.63 mg/3ml, and 0.31 mg/3 ml dosage products eight years in advance of the expiration of the last to expire of the Sepracor Patents. The settlement also avoids the substantial uncertainty and risk involved with prolonged patent infringement litigation and eliminates the substantial litigation costs incurred by both Plaintiff and Defendant during the patent litigation while also serving the public interest by saving judicial resources.

11. All affirmative defenses, claims, and counterclaims in the Litigation that have been or could have been raised by the parties in the Litigation are hereby dismissed without prejudice.

12. Each of the parties shall bear its own costs and attorney fees.

13. Both Plaintiff and Defendant consent to personal jurisdiction and venue in the United States District Court for the District of Massachusetts for the purpose of enforcing the Settlement and License Agreement. This Court shall retain jurisdiction over any matters related to or arising from the interpretation or enforcement of the Settlement and License Agreement.

IT IS SO STIPULATED:

Dalila Arguez Wendlandt (BBO# 639280)
F. Turner Buford (BBO# 661311)
Ropes & Gray LLP
One International Place
Boston, MA 02110-2624
(617) 951-7242 (Phone)
(617) 951-7050 (Facsimile)

Attorneys for Plaintiff Sepracor Inc.

Joseph M. O'Malley, Jr. (admitted *pro hac vice*)
Bruce M. Wexler (admitted *pro hac vice*)
Paul, Hastings, Janofsky &
Walker LLP
75 East 55th Street
New York, NY 10022
(212) 318-6000 (Phone)
(212) 319-4090 (Facsimile)

Attorneys for Plaintiff Sepracor Inc.

SO ORDERED

Dated: _____

Alan D. Rose (BBO # 427280)
Michael L. Chinitz (BBO # 552915)
ROSE, CHINITZ & ROSE
29 Commonwealth Avenue
Boston, MA 02116
Telephone (617) 536-0040
Facsimile (617) 536-4400

Attorneys for Defendant, Breath Limited

E. Anthony Figg (admitted *pro hac vice*)
Joseph A. Hynds (admitted *pro hac vice*)
Sharon L. Davis (admitted *pro hac vice*)
R. Elizabeth Brenner-Leifer (admitted *pro hac vice*)
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1425 K Street, N.W. Suite 800
Washington, DC 20005
Telephone (202) 783-6040
Facsimile (202) 783-6031

Attorneys for Defendant, Breath Limited

Hon. Douglas P. Woodlock
United States District Judge

ATTACHMENT B

**Filed as Exhibit 10.5 to Sepracor Inc.'s Quarterly Report on Form 10-Q
for the fiscal period ended June 30, 2008**

QuickLinks

[Exhibit 10.4](#)

EXHIBIT 3

**DEY, L.P.'S AND DEY, INC.'S BRIEF IN OPPOSITION TO
SEPRACOR'S MOTION TO DISMISS**

RECEIVED BY HAND

MAR 18 2008

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

A&G

COPY

SEPRACOR, INC.,)
)
Plaintiff,)
) C.A. No. 07-438
v.)
)
BARR LABORATORIES, INC.,)
)
Defendant.)

SEPRACOR, INC.,)
)
Plaintiff,)
) C.A. No. 06-113
v.)
)
DEY, L.P., and DEY, INC.,)
)
Defendants.)

Friday, March 7, 2008
10:43 a.m.
Courtroom 4B

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE JOSEPH J. FARNAN, JR.
United States District Court Judge

Hawkins Reporting Service
715 North King Street - Wilmington, Delaware 19801
(302) 658-6697 FAX (302) 658-8418

APPEARANCES:

MORRIS NICHOLS ARSHT & TUNNELL
BY: JACK BLUMENFELD, ESQ.
BY: KAREN JACOBS LOUDEN, ESQ,

-and-

PAUL HASTINGS
BY: QUINN CLANCY, ESQ.

Counsel for the Plaintiff

MORRIS JAMES
BY: RICHARD HERRMANN, ESQ.

-and-

WINSTON STRONG
BY: IMRON ALY, ESQ.

Counsel for the Defendant
Barr Laboratories, Inc.

ASHBY & GEDDES
BY: JOHN G. DAY, ESQ.

-and-

FROMMER, LAWRENCE & HAUG
BY: ELIZABETH LEFF, ESQ.

Counsel for the Defendant
Dey, Inc.

1 THE COURT: All right. We'll take
2 the next group, which is Sepracor and Barr and
3 Sepracor and Dey. This is going to be a lot
4 easier.

5 All right. You want to announce
6 your appearances for the record.

7 MR. BLUMENFELD: Thank you, Your
8 Honor. For Sepracor, Jack Blumenfeld and Karen
9 Jacobs Louden from Morris Nichols, and Quinn
10 Clancy from Paul Hastings in New York.

11 THE COURT: Good morning.

12 MR. DAY: Good morning, Your
13 Honor. John Day from Ashby & Geddes for the
14 Dey, D-E-Y, defendants in Civil Actions 06-113
15 and 06-604.

16 With me are Elizabeth Leff from
17 Frommer, Lawrence & Haug Washington D.C.

18 THE COURT: Good morning.

19 MR. HERRMANN: Good morning, Your
20 Honor. I'm here for Barr, and I would like to
21 introduce Imron Aly from Winston Strong.

22 THE COURT: All right. So trying
23 to decide whether Dey and Barr can come together
24 to defend against Sepracor. And I guess the

1 reason why I didn't decide this on the papers as
2 I was looking over the papers and thinking about
3 it is I can understand the efficiencies, but I
4 have two concerns, one is the concern expressed
5 about Barr's ability to try its case, and
6 secondly, the time considerations.

7 So we'll go with Sepracor.

8 MR. BLUMENFELD: Thank you, Your
9 Honor. This is a little bit of an unusual
10 situation because Sepracor and Barr want
11 consolidation and Dey doesn't. We can vote,
12 that would take care of things. But I
13 understand Your Honor's concerns, and we
14 certainly do see it as an efficiency point,
15 judicial efficiency, party efficiency where we
16 have five patents in each case, we have claim
17 construction, infringement validity issues that
18 overlap, it is going to be a bench trial so we
19 don't have any of the normal confusing a jury,
20 getting everyone -- the arguments that
21 defendants will make about being prejudiced
22 about being with another defendant.

23 But in terms of the schedule, you
24 know, claim construction briefing hasn't started

1 in either case. And I think that we had agreed,
2 this was before Your Honor issued the order, the
3 scheduling order in the Barr case this week, we
4 had agreed that briefing would take place on the
5 same schedule in both cases and it was going to
6 be in April and May, and certainly we think that
7 the claim construction process we ought to go
8 through once, I mean from Your Honor's point of
9 view, certainly from our point of view. And I
10 would think both defendants want to have their
11 shot at the same time rather than going through
12 that twice.

13 There is no Markman hearing set in
14 the Dey case. Your Honor set Markman hearing
15 and a pretrial conference and a trial in the
16 Barr case. The Markman hearing in early
17 September, and it does seem to us at the very
18 least no matter what else is going to happen
19 here that we ought to go forward and have that
20 Markman hearing in both cases.

21 And the arguments that Dey makes,
22 I guess those are the ones that maybe -- I don't
23 know if that's -- I don't know if it's the Barr
24 period to catch up or if it's Dey's prejudice

1 argument that is what is concerning Your Honor,
2 but on the Dey prejudice, the fact is that there
3 is a third case up in Massachusetts, the Brett
4 case and the Markman hearing in that is
5 scheduled for later this month.

6 There is a trial he set I believe
7 for July and August. And Brett is the first
8 filed ANDA filer, or Brett has the 180 days of
9 exclusivity, but that is really a very tiny part
10 of the market and so where we are is trying to
11 put things together so that at least with
12 respect to the things that do overlap, the claim
13 construction and where we go after claim
14 construction, that we go through that once.

15 From our point of view it
16 certainly makes sense to do the claim
17 construction together, to get a decision from
18 Your Honor, and then to move forward hopefully
19 to try cases together so that we only have to
20 try the issues once.

21 And I think there is enough time
22 that that can be done. Certainly it's early
23 2008 now, with a Markman hearing in September
24 and then the things that follow after that, we

1 and Barr proposed a pretrial conference in
2 February or March of next year, and we don't see
3 any reason why that can't be done and the case
4 move forward, both cases move forward so that we
5 have one trial on the same issues. And that's
6 about where we are from the separate side, Your
7 Honor.

8 THE COURT: All right. Thank you.

9 MR. BLUMENFELD: Thank you.

10 MS. LEFF: Good morning, Your
11 Honor. I don't think a vote would work since
12 Barr hasn't gotten its exclusivity yet and so
13 they're not really in a position to compete
14 whereas we did get tentative approval on our
15 product.

16 I think that this case, this case
17 has been in the court system for two years. And
18 it was unfortunate that it got caught up in
19 Judge Jordan's good news of being elevated and
20 basically sat for quite a while.

21 Judge Thyng did a great job in
22 trying to push it along, but without having a
23 judge that would try the case, she was not in a
24 position to deny motions for continuances and to

1 push the schedule out, so the schedule has been
2 pushed out to the point where we're going to
3 brief our Markmans about the time that we were
4 supposed to have trial.

5 We don't have an opposition to
6 briefing Markman at the same time as bar, but we
7 do have an opposition to change our schedule and
8 to move to have -- to have a Markman hearing in
9 September, that's very late for us and it will
10 push us back probably until the June date that
11 Your Honor has chosen for the Barr case.

12 And if Your Honor tries this case
13 in June, it will be well over two years in the
14 system, well over three years in the system.

15 THE COURT: I don't recall the
16 filing date. What was roughly your filing date?

17 MS. LEFF: Our filing date was
18 February 2006. And I think as the papers have
19 shown and the correspondence has shown, Sepracor
20 has tried to drag this case on and tried to take
21 advantage of the Court's inability to have all
22 of the judges here.

23 Now, with respect to the products
24 in going to market, as I said, our client has

1 gotten tentative approval on both its 3ML
2 products and its concentrate product. I know
3 that Mr. Blumenfeld has stated that the
4 concentrate product is such a small part of the
5 market that it shouldn't make any difference at
6 all, but it does make a difference. And if Your
7 Honor could turn to the attachment to
8 Mr. Blumenfeld's -- to Mr. Preston Ratliff's
9 declaration, it's marked SEP 10000005, these are
10 the revenue figures that Sepracor uses to
11 indicate that the sales of the concentrate are
12 very low and insignificant.

13 But I would like to point out a
14 couple of things to Your Honor. In 2004, the
15 product was only on the market for two months
16 and then was removed from the market by Sepracor
17 voluntarily because there were problems with its
18 manufacture. The product was off the market for
19 the entire year of 2005 and didn't come back on
20 the market until 2006 in June. So the numbers
21 for 2006 are for half a year.

22 The number for 2007 is for a full
23 year, but I would ask Your Honor to compare the
24 number in 2007 for the concentrate revenue to

1 the revenue for the MDI which was also in its
2 first year in 2005 and you'll see that the
3 numbers are the same. The product is just
4 coming back after having been removed from the
5 market because of problems.

6 You have to convince the
7 physicians that the problems have been taken
8 care of and that this product can be used by
9 their patients safely. And in addition, it
10 seems to be following the sales of the MDI which
11 I don't think anybody would argue are small.

12 With respect to the 3ML product,
13 Mr. Blumenfeld argues that Sepracor -- that Dey
14 cannot go to market because Brett is first to
15 file. The statute is very complicated, but if
16 Dey wins its case and the '289, the six patent
17 is also taken care of, then that triggers
18 Brett's exclusivity.

19 And what I think is happening here
20 is that there is going to be some sort of a
21 settlement between Brett and Sepracor and
22 they're going to be able to park their ANDA and
23 there is going to be no generic for Albuterol on
24 the market until the Dey case goes through the

1 cycle, so the longer this case is put off, the
2 more harm there is to the public and the impact
3 on Dey.

4 THE COURT: What's your -- what's
5 your strongest case to attack the patent?

6 MS. LEFF: What's our strongest
7 case to attack which patent? The '289, the one
8 that they haven't sued us on.

9 THE COURT: No. I have a hard
10 time understanding why you're dissimilar from
11 Barr on your patent attacks.

12 MS. LEFF: I don't know if we're
13 dissimilar from Barr on our patent attacks, but
14 I don't know what Barr is arguing, I know we
15 have made different arguments than Brett has
16 made.

17 THE COURT: Tell me what your
18 arguments are.

19 MS. LEFF: What our invalidity
20 arguments are? We have an anticipation argument
21 and we have an obviousness argument, and --

22 THE COURT: Tell me about your
23 obviousness argument.

24 MS. LEFF: Our obviousness

1 argument is on two British patents that were
2 published in 1970.

3 THE COURT: And what do you
4 understand Brett's attack to be, or case to be?

5 MS. LEFF: With respect to that,
6 Brett I think is only making an anticipation
7 argument, but I'm not sure.

8 THE COURT: If Mr. Blumenfeld is
9 correct about the Massachusetts case with Brett
10 and if the Wall Street Journal's information is
11 incorrect that you rely on to talk about
12 settlement and the Markman briefing occurs in
13 April and May, or May and June, and you have a
14 Markman hearing in September, with the
15 understanding that if Brett could settle, you
16 could get into trial sooner, since the Markman
17 will be uncompleted and it's a bench trial, in
18 other words, you can be separated from Barr
19 later and moved up, how are you prejudiced?

20 MS. LEFF: I'm prejudiced because
21 of the concentrate. The concentrate, Brett does
22 not have an ANDA for the concentrate, so we
23 wouldn't be able to go to market on that in a
24 timely manner.

1 THE COURT: He answered that by
2 saying, and I understand your side is well,
3 there is a good market share, Mr. Blumenfeld
4 says that's not the case.

5 MS. LEFF: Well, Mr. Blumenfeld
6 didn't acknowledge the fact that in 2004 that
7 product was only on the market for two months,
8 that it wasn't sold in 2005, that it was only on
9 the market in 2006 for six months and in 2007
10 when it was in the market for the whole year, it
11 had about the same sales as the MDI that's
12 listed for 2005 when it first came into the
13 market, and the MDI I don't think anybody would
14 argue is not a popular product.

15 THE COURT: All right. Let me
16 hear from Barr. Thank you.

17 MR. ALY: Good morning, Your
18 Honor. From Barr's point of view, it can be
19 done quite efficiently as follows, and that is
20 to summarize, Your Honor pointed out, there is
21 still work to be done in the Dey case, the
22 Markman briefing needs to be scheduled and done,
23 the Markman hearing needs to be scheduled and
24 done, and then there needs to be a decision time

1 for ruling on the Markman hearing and decision.

2 And that amount of time will be
3 enough for Barr to do the fact discovery that it
4 needs to do in this case so long as it gets what
5 has already happened in the Dey case and that's
6 where the opposition had come in specifically
7 seeking the discovery, three things, documents
8 that are produced already in that case, the
9 depositions and expert reports that have been
10 taken, and the positions, the claim construction
11 positions, they have already done some
12 exchanges, they know what that situation is and
13 in exchange for that, Barr will accelerate and
14 do the fact discovery.

15 So when it comes to delay, the
16 bottom line from Barr's point of view is there
17 really is no delay. There is no dates that Dey
18 has that we need to change and if there are
19 dates that Your Honor is scheduling for trial,
20 for Markman hearing, Barr only ask that it be a
21 part of that, so that now that we're here in the
22 situation with the same five patents at issue
23 and we have invalidity arguments that Barr wants
24 to present, that should be treated at the same

1 time and if anyone is prejudiced by that, it's
2 Barr because it has to do all that work in a
3 much more compressed time frame and it's willing
4 to do that because of the situation that we're
5 in.

6 A related point I wanted to make
7 sure Your Honor is aware, as far as case filing,
8 as pointed out in Dey's papers there are
9 actually two cases filed against Dey, one is
10 February 6, there is also September 2nd, 2006.
11 The reason that's important, this concentrate
12 issue that's been raised is related to that
13 second case which is much later in time and
14 comes closer to the Barr filing which was July
15 2007. So even looking at it from a calendar, if
16 an Article 3 judge had been assigned to this
17 case from beginning to end we would probably
18 still consolidate and be in this same position.
19 There is no overall Dey (GET THIS) and as far
20 this particular case is concerned, now that it's
21 presented to Your Honor, Your Honor has these
22 cases, there are no dates set and whatever there
23 are dates set Barr says let us be a part of it.

24 In conclusion, Your Honor, the

1 case in Massachusetts is the case that is the
2 first filer, we're here tied for second, if you
3 will, and our cases do not need to be at the
4 same track as the Brett case, but whatever the
5 track is that's decided, keeping in mind a we
6 don't need to be as accelerated as the Brett
7 case, Barr seeks to be a party to that. All the
8 parties agree we should be consolidated for
9 Markman, so we know that the Markman briefing
10 and the time allowed for that, and in the
11 interim we'll take the facts discovery that we
12 need so long as Barr gets its paper.

13 Your Honor, questions about those
14 clarifications, hopefully we will put at ease
15 the points that Your Honor had raise in the
16 introductions.

17 THE COURT: All right.

18 MR. DAY: Your Honor, if I may
19 correct one thing that he said. In the Dey case
20 we do have a Markman briefing scheduled, opening
21 briefs are scheduled for April the 10th, Judge
22 Thyng did put a briefing schedule, actually
23 Judge Jordan put a briefing schedule in place,
24 Judge Thyng extended it a little bit, but we do

1 have a briefing schedule in place, that is not
2 unscheduled as he said.

3 MR. ALY: And Barr has agreed to
4 that.

5 THE COURT: You agree to go in the
6 April/May time frame?

7 MR. ALY: Sure. Absolutely. If
8 that's how quick it needs to be, we have agreed
9 to that, and Sepracor has agreed to it that we
10 would be on that schedule.

11 MS. LEFF: Your Honor, first, we
12 never agreed that we would consolidate the
13 Markman hearings, we said that if Barr wanted to
14 brief their Markman in the same time, that's
15 fine, there is nothing we can do about that,
16 that's fine. We don't want to put off our
17 Markman hearing until September, that's quite a
18 ways off from reply briefs due May 1st.

19 And in addition, I would
20 definitely disagree that we would be on the same
21 schedule in terms of consolidation if Judge
22 Jordan were not on the circuit bench because
23 Judge Jordan would have had us in trial in about
24 two weeks.

1 THE COURT: From today?

2 MS. LEFF: Actually no, I'm sorry,
3 that was the first date. We were going to be in
4 trial at the end of April. That's when this
5 case -- this case was scheduled for trial, it
6 was scheduled for Markman, it was scheduled for
7 everything, but Judge Thyngge took them off, so
8 it's not that we haven't been scheduled.

9 THE COURT: Help me out here. The
10 case went to Judge Jordan and he put a schedule
11 in place, that schedule would have allowed for
12 trial in April of 2008 from February 2006.

13 MS. LEFF: Yes.

14 THE COURT: And is that on the
15 concentrate?

16 MS. LEFF: That's on both. He
17 actually set the trial initially for February
18 before the concentrate, and he extended it by
19 two months when they sued on the concentrate
20 because the concentrate is essentially the same
21 product, but he gave them two extra months.

22 THE COURT: And when did Judge
23 Thyngge get the case?

24 MS. LEFF: Judge Thyngge got the

1 case in November of 2007.

2 THE COURT: Seven.

3 MS. LEFF: Six, 2006, I'm sorry.

4 THE COURT: And then at some point
5 moved those dates out.

6 MS. LEFF: They were moved out,
7 there were continuous requests from Sepracor to
8 extend the schedule for this and extend the date
9 for that, and we -- Judge Thyng granted the
10 first one and we didn't see any point in
11 objecting to those because we didn't want to
12 bring Judge Thyng's busy schedule into it, but
13 you can see on the docket that the orders do
14 indicate for a large number of them that Dey did
15 it as a courtesy and that it was Sepracor that
16 wanted the extension.

17 THE COURT: All right. Thank you.
18 Mr. Blumenfeld.

19 MR. BLUMENFELD: Your Honor, it
20 sounds like the one thing that everyone can
21 agree and hopefully Your Honor agrees on is that
22 we're going to go forward with simultaneous
23 Markman briefing, I would hope with a
24 simultaneous Markman hearing. And I ask what we

1 have from the Sepracor side and, in fact, the
2 reason Mr. O'Malley and Mr. Ratliff aren't here
3 today is because there are three deposition
4 going in the Sepracor litigation today, there is
5 a lot going on including a trial in
6 Massachusetts this summer.

7 What I would hope we could do is
8 agree to have a Markman hearing after that
9 trial, give people a little breather, and
10 September 10th is fine with us, and at that time
11 we go forward and at that time the Brett trial
12 presumably would be over and we'll have a lot
13 better handle on where things are.

14 And the fact is that Brett is the
15 first filer, and Brett is holding everyone else
16 up. There is no question about that. Dey can't
17 get FDA approval on any of its products until
18 the Brett situation is resolved. That's the way
19 the statute works. And that's true of its
20 concentrate for reasons we explained in the
21 brief, also.

22 And so it seems to make a lot of
23 sense to us to go forward with the joint claim
24 construction, get Your Honor's decision and see

1 where we are in the Brett case at that time. If
2 at that time there is a reason as Your Honor
3 suggested that Barr has why it should be
4 separated and get to trial earlier, we can deal
5 with that, but right now there doesn't seem to
6 be any reason because everyone seems to be
7 pretty much in the same position right now.
8 That certainly is my suggestion.

9 THE COURT: Well, okay.

10 MS. LEFF: Your Honor, I disagree
11 with Mr. Blumenfeld on the law. The concentrate
12 is not in the same position, we were first to
13 file in the concentrate, and so we have
14 exclusivity, and we also have tentative
15 approval, so we can go to market either after
16 the thirty-month stay is over or after there is
17 a decision in this case.

18 THE COURT: When would the
19 thirty-month stay expire?

20 MS. LEFF: February 2009.

21 THE COURT: Well, here is the good
22 news. I don't feel like I'm that busy so I have
23 got all sorts of time. I guess other judges are
24 more clogged up than this district.

1 I analyze these cases on the basis
2 of the defenses, and when I was reading the
3 papers, I don't consider to be very complex
4 validity challenges to a patented drug to be --
5 until you get to double patent and I think
6 anticipation, obviousness and those kind of run
7 of the mill things as infringement as they are
8 in all cases, so I don't view this as a very
9 difficult case to get to trial and to get
10 decided. Unless I misunderstood something in
11 what I read or what I asked here this morning.

12 As I understand it, it's basically
13 the attacks on the patent are attacks of
14 anticipation and obviousness.

15 Now, to some extent I agree with
16 Sepracor that the timing in these cases now that
17 I have them which hasn't been all that long is a
18 little bit driven by the Brett case and whether
19 or not that goes forward to trial in the summer,
20 I'm not too concerned about the claim
21 construction or whether it settles.

22 So what I'm going to do is provide
23 you with a decision that consolidates the cases,
24 Barr and Dey along the lines that Barr has

1 agreed to, you'll catch up on your fact
2 discovery, have your quote unquote case. You
3 will brief in the time frame scheduled in the
4 Dey case which is the April/May date. Once that
5 briefing is completed, you'll call and write
6 chambers for a Markman date.

7 At that point I'll decide when the
8 Markman hearing is going to be. And as I have
9 said, that's going to be driven largely by
10 what's going on in Massachusetts. If
11 Massachusetts is still heading toward trial,
12 your Markman date will be further out. If
13 Massachusetts has settled out, then I'll move
14 the Markman date nearer to the Markman briefing.

15 All of you should be ready to go
16 to trial on ninety days notice from the Markman
17 decision. And again, that date will largely be
18 driven by the Massachusetts status.

19 And I think that provides
20 attention to everybody's issues in a time frame
21 that I can deal with having been the beneficiary
22 of the inheritance of these cases. If I had
23 been in them earlier, I probably would have done
24 things a little differently, but given the

1 status that I have taken, I think that's the
2 fairest way to approach it so that we are
3 briefed on Markman, ready to go with Markman,
4 and you're all on notice that from any given
5 point in ninety days you got to be ready to go
6 to trial.

7 And we'll talk about how the trial
8 is going to go because it's a bench trial, and
9 given the noncomplex nature, at least in my
10 view, of the defenses, I think we can take care
11 of everybody's concerns as they arise and do it
12 in a way that saves everybody money and time.

13 And the good news for you,
14 although I have no expertise in circuitry, I'm
15 kind of a hobby nut about pharmaceuticals, so
16 I'm up to speed a little more. Not that I
17 medicate a lot, but I just like to read about
18 it.

19 All right. So Mr. Blumenfeld, I'm
20 going to charge you with working with your
21 friends to get an order that establishes my
22 order.

23 MS. LEFF: Your Honor, if I could
24 raise an additional issue.

1 THE COURT: You're on.

2 MS. LEFF: If I could raise an
3 additional issue. We're having some problems
4 with expert depositions. I think you got some
5 information about this. Expert depositions were
6 supposed to be completed by March 13th which is
7 next week. As of today, Sepracor will have
8 taken all but one of our witnesses who has
9 offered three days that they have turned down.

10 We have still four witnesses of
11 Sepracor's to take because they tell us their
12 witnesses aren't available until April which is
13 outside the scheduling order in the first place.
14 So we need some guidance in order to figure out
15 when these depositions will take place.

16 THE COURT: These are expert
17 depositions?

18 MS. LEFF: These are expert
19 depositions.

20 THE COURT: Again, in my world of
21 patent cases, I typically in my scheduling order
22 have expert reports exchanged and discovery
23 occur, that is the deposition after my Markman
24 ruling. Now, in ANDA cases that can vary a

1 little bit depending on timing, but you know,
2 typically they are allowed forty-five to sixty
3 days of expert discovery.

4 But I understand you have a
5 scheduling order, but I think it's going to be
6 modified by the consolidation decision.

7 MS. LEFF: But, Your Honor, our
8 expert reports are already done, and we've
9 already had most of the experts, a good number
10 of the experts have been deposed.

11 THE COURT: Right. So do they
12 know what I'm going to say about the Markman
13 disputes?

14 MS. LEFF: No, they don't.

15 THE COURT: That's what I'm
16 saying, it's interesting that you have all your
17 expert depositions done and your expert
18 discovery done, but do you think it might change
19 if I disagree with what they think the words of
20 the patent might say?

21 MS. LEFF: Your Honor, we are
22 going according to Judge Jordan's schedule.

23 THE COURT: That's what I'm trying
24 to say politely, I'm trying to say I think

1 you're out of that. Again, I have done a few
2 patent cases, and I have even had to try some,
3 and I don't understand -- I came to it late, but
4 when I came to it, I was committed -- how you
5 can have meaningfully expert discovery until you
6 know what the trial judge says the disputes, or
7 how the disputes are resolved. Sometimes I
8 don't give an answer, I just say it's the
9 ordinary meaning, but when I do give an answer,
10 inevitably it changes because the experts come
11 with different views.

12 MS. LEFF: Your Honor, if I may,
13 the experts also who are skilled in the art can
14 also give their opinion on what certain terms
15 might mean to them.

16 THE COURT: I didn't take an
17 expert opinion on Markman disputes since Markman
18 came down, I clearly violated the federal
19 circuit's rules. I used to have Markman
20 hearings with experts because I thought it was
21 important to understand what they said, I agree
22 with you, it may be at the Markman hearing you
23 may want to present some expert testimony, but
24 what I'm saying to get to the facts and the law

1 to get appealed to the federal circuit, it's
2 kind of hard to do until I speak.

3 I'm not being egotistical here,
4 I'm being very practical. What happened in jury
5 trials and even in bench trials, the other side
6 would say before you got the Judge's claim
7 construction, didn't you think that about meant,
8 you know, 50 milliliters, but they used to say
9 different things, so now we get to where you
10 know what I think the patent says and then you
11 have to deal with it.

12 I understand what you're saying,
13 but I think you're kind of out of that
14 scheduling order.

15 MS. LEFF: Does that mean we will
16 rebrief -- I'm sorry, that we'll have new expert
17 reports after the Markman?

18 THE COURT: Well, unless your side
19 convinces me that your view of all the disputes
20 are all correct, I would think you would have to
21 change it, because I'm not going to have an
22 expert come to the bench trial and say Judge,
23 you were wrong about that so I'm going to give
24 you my view on infringement anyway, I'm going to

1 give you my view of obviousness on those two
2 British patents even though you think it says
3 something else. Yes, you're going to have to,
4 unless I agree with your expert, you're going to
5 have to deal with --

6 MS. LEFF: Your Honor, are you
7 saying we should stop the expert depositions at
8 this point and wait?

9 THE COURT: I think that's what I
10 said, but I could not understanding the
11 question. I mean, what I'm saying is I don't
12 know how you can have an expert report until you
13 have my claim construction.

14 MS. LEFF: That's what we were
15 ordered to do.

16 THE COURT: And I'm not
17 criticizing that. I don't know enough about
18 what the other judge did. Does everybody do it
19 differently?

20 MR. BLUMENFELD: Well, certainly
21 Judge Sleet does it the way that is -- that you
22 have just said and is now in the scheduling
23 order that is on your website. Judge Robinson
24 does it a little differently.

1 THE COURT: She does her Markman
2 in conjunction with summary judgment, that's why
3 she's -- she takes the expert report, but then
4 does she forbid you from using them at trial if
5 they --

6 MR. BLUMENFELD: The problem is,
7 you know, I'm sure Mr. Herrmann and Mr. Day have
8 been through this. The problem is that when the
9 Markman comes down, inevitably the experts have
10 to adjust their opinions.

11 THE COURT: That's what led me to
12 this procedure.

13 MR. BLUMENFELD: And that happens
14 in most cases, that people do have to adjust
15 things.

16 THE COURT: Unless you win all
17 out.

18 MR. BLUMENFELD: Right.

19 MS. LEFF: Or unless they give
20 alternate opinions, if the Court construes it
21 this way.

22 THE COURT: If they did that, then
23 you still have the ability to do it. But I try
24 to save the people money by saying don't get

1 those experts engaged for a lot of money until
2 you know -- and again, I want to make clear it's
3 not because I think I'm driving the bus, except
4 that a little bit I am, every trial judge is on
5 the Markman decision.

6 I have to tell you actually one of
7 the Federal Circuit judges thought it was a
8 great idea. I was on a panel with him, and
9 because of the confusion that gets in the
10 limited record they accept, that makes it real
11 clear what the expert is saying and it's
12 conditioned on the claim construction.

13 Anyway, I apologize to you. I
14 think to answer your question directly which is
15 what I like to do, it may be your expert's stuff
16 is okay if I agree with everything your expert
17 said, but it's clear that expert discovery is
18 probably something that shouldn't be -- not
19 probably, is something that shouldn't be engaged
20 in until after we have the Markman hearing, so
21 I'm going to take your April and May briefing,
22 you're going to call me and get a date, you're
23 going to tell me what's going in Massachusetts,
24 I'm going to set a Markman hearing, I'm going to

1 get a timely decision after the Markman hearing
2 and at the same time give you a date for the
3 bench trial, again, driven by the Massachusetts
4 action.

5 And if you settle with the folks
6 in Massachusetts, you'll let us know immediately
7 and that will speed up my attention to the case.
8 As I said, I just feel I can get you on since
9 it's a bench trial in my schedule.

10 MS. LEFF: Thank you, Your Honor.

11 THE COURT: And I'll get an order.

12 MR. BLUMENFELD: We'll do an
13 order.

14 THE COURT: Thank you.

15 (Court recessed at 11:29 a.m.)
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1 State of Delaware)
2 New Castle County)

3
4 CERTIFICATE OF REPORTER

5 I, Dale C. Hawkins, Registered Merit
6 Reporter and Notary Public, do hereby certify that
7 the foregoing record is a true and accurate
8 transcript of my stenographic notes taken on March 7,
9 2008, in the above-captioned matter.

10 IN WITNESS WHEREOF, I have hereunto set my
11 hand and seal this 14th day of March, 2008, at
12 Wilmington.

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EXHIBIT 4

**DEY, L.P.'S AND DEY, INC.'S BRIEF IN OPPOSITION TO
SEPRACOR'S MOTION TO DISMISS**

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August 12, 2008

VIA E-MAIL, FACSIMILE, & OVERNIGHT COURIER

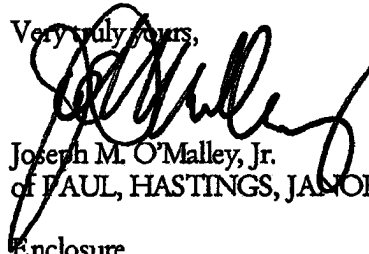
Elizabeth A. Leff, Esq.
Frommer Lawrence & Haug LLP
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Washington, D.C. 20006

Re: *Dey L.P. & Dey, Inc. v. Sepnacor Inc.*,
Civil Action No. 1:08-cv-372-JJF

Dear Elizabeth:

Enclosed is a covenant not to sue regarding U.S. Patent 6,451,289.

Very truly yours,



Joseph M. O'Malley, Jr.
of PAUL, HASTINGS, JANOFSKY & WALKER LLP

Enclosure

cc: Via E-mail

Jack B. Blumenfeld, Esq.
Steven J. Balick, Esq.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

DEY, L.P. and DEY, INC.

Plaintiffs,

v.

SEPRACOR INC.,

Defendant.

C.A. No. 08-372-JJF

COVENANT NOT TO SUE REGARDING U.S. PATENT NO. 6,451,289

WHEREAS, Sepracor Inc. ("Sepracor") owns all rights, title and interest in U.S. Patent No. 6,451,289 (the "'289 patent");

WHEREAS, Dey, L.P. and Dey, Inc. (collectively "Dey") submitted abbreviated new drug application ("ANDA") Nos. 77-800 and 78-309 to the United States Food and Drug Administration for 0.31 mg/3 mL, 0.63 mg/3 mL, 1.25 mg/3 mL, and 1.25 mg/0.5 mL strengths of levalbuterol hydrochloride inhalation solutions;

WHEREAS, Dey filed this civil action, captioned *Dey, L.P. and Dey, Inc. v. Sepracor Inc.*, C.A. No. 08-372-JJF on June 20, 2008, alleging that the products described in Dey's ANDA No. 77-800 do not infringe the '289 patent;

WHEREAS, pursuant to a confidentiality agreement in another lawsuit, *Sepracor Inc. v. Dey, L.P., et al.*, C.A. No. 06-113-JJF, Dey produced to Sepracor portions of Dey's ANDA No. 77-800 as pages numbered DLEV000001 – DLEV000037 and ANDA No. 78-309 as pages DLEV008918 – DLEV008945.

NOW, THEREFORE, Sepracor represents, stipulates, agrees and covenants as follows:

1. Sepracor unconditionally represents, stipulates, agrees and covenants that it will not sue Dey for infringement of, or otherwise assert, enforce, or hold Dey liable for infringement of the '289 patent based on the importation, manufacture, use, sale, or offer for sale of the levalbuterol hydrochloride inhalation solution products that are the subject of and described in Dey's ANDA No. 77-800, as produced to Sepracor as pages labeled DLEV000001 – DLEV000037, or Dey's ANDA No. 78-309, as produced to Sepracor as pages labeled DLEV008918 – DLEV008945.

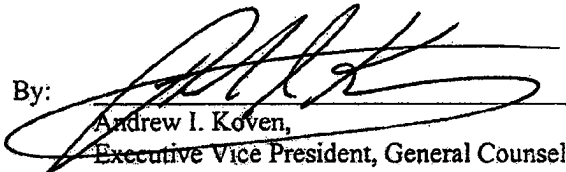
2. This covenant has no bearing upon whether Dey's filing of ANDA Nos. 77-800 or 78-309, or the importation, manufacture, use, sale, or offer for sale of the levalbuterol hydrochloride inhalation solution products that are the subject of and described in Dey's ANDA Nos. 77-800 or 78-309 infringes any claim of the '289 patent.

3. This covenant has no bearing upon the validity or enforceability of any claim of the '289 patent.

Dated: August 12, 2008

SEPRACOR INC.

By:

A handwritten signature in black ink, appearing to read "A. Koven", is written over a horizontal line.

Andrew I. Koven,

Executive Vice President, General Counsel and Corporate Secretary

EXHIBIT 5

**DEY, L.P.'S AND DEY, INC.'S BRIEF IN OPPOSITION TO
SEPRACOR'S MOTION TO DISMISS**

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SEPRACOR INC.,

Plaintiff,

v.

DEY, L.P., and DEY, INC.

Defendants.

C.A. No. 06-113 (JJF)

C.A. No. 06-604 (JJF)

CONSOLIDATED

SEPRACOR INC.,

Plaintiff,

v.

BARR LABORATORIES, INC.,

Defendant.

C.A. No. 07-438 (JJF)

**SEPRACOR'S REPLY BRIEF IN SUPPORT OF ITS
MOTION TO CONSOLIDATE THE DEY AND BARR CASES**

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February 29, 2008

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1.

INTRODUCTION

Barr and Dey's answering briefs present no compelling reason why these cases, involving the same five patents and similar if not identical issues, should be the subject of two separate trials. Although Barr captioned its answering brief as an "opposition," Barr agrees that consolidation is appropriate and offers for the Court's consideration an alternative case schedule, which Sepracor does not oppose. Dey argues that consolidation is inappropriate on the bald assertion that it would somehow delay the commercialization of its products. This is incorrect and ignores the fact that Breath has sole ANDA "first-filer" status for all commercially relevant products at issue. For the reasons explained in Sepracor's opening brief and below, this Court should consolidate the Barr and Dey cases for all purposes, including a single bench trial.

ARGUMENT

Neither Barr nor Dey deny that it is most efficient for this Court to hear similar, if not identical issues, involving the same patents in a single trial. Nor can they deny that hearing the cases together will have little impact on the current schedule (where no Markman briefs have been filed and no Markman hearing, pretrial conference or trial date is even set), or have any impact on the commercial introduction of their generic products.

Barr *agrees* that the Dey and Barr cases should be consolidated. Barr only requests that the consolidated schedule proposed by Sepracor be extended by one month, which Sepracor does not oppose,¹ and seeks modifications on the discovery deposition limits Sepracor proposed.²

¹ As a condition of its proposed consolidated schedule, Barr requests that it be provided access to the relevant documents from the Breath and Dey cases. [C.A. No. 07-438-JJF, D.I. 48 at 3-4.] Sepracor has agreed to produce these documents. To date, Sepracor has produced over 500,000 pages of documents to Barr and many of the transcripts of
(Continued . . .)

2.

Dey, on the other hand, opposes consolidation based primarily on the argument that market entry of its proposed generic concentrate solution would be delayed.³ This is a red herring. Dey's proposed concentrate solution is relatively insignificant compared to the other dosage strengths it seeks to sell – the concentrate makes up only 2 to 3% of the total sales for Sepracor's Xopenex® inhalation solution products. [Exh. 1.]⁴ Indeed, the other ANDA filers, Breath, Barr, and Watson (who did not challenge the five method of use patents and therefore was not sued), view the concentrate as less commercially significant because none of these other generic challengers filed an ANDA seeking approval to sell the concentrate.

Dey concedes that the 30-month stay for its proposed generic concentrate solution does not expire until February 2009. In positing that if “judgment favorable to Dey is rendered in August 2008, Dey could go to market with the concentrate solution in August 2008” (D.I. 255 at 8), Dey fails to acknowledge that no Markman hearing, pretrial conference or trial date has

(... continued)

depositions taken by Dey and Breath. By the end of the week, Sepracor will produce pursuant to D. Del. LR 26.2 the transcripts of all of the depositions taken by Dey and Breath as well as its claim construction briefs from the Breath case. Sepracor will continue to produce on a rolling basis the relevant document productions, expert reports, and discovery responses from the Breath and Dey cases.

² Sepracor continues to believe that Barr should be limited to a total of 50 hours for fact depositions. In the spirit of cooperation, Sepracor advised Barr during a February 27, 2008 teleconference that it would agree to a half-day of deposition (3.5 hours) for any witness that has already been deposed in either the Breath or Dey cases.

³ There is no dispute that Breath has sole ANDA “first filer” status for the 0.31 mg/3 mL, 0.63 mg/3 mL, and 1.25 mg/3 mL commercial presentations of Xopenex®. Likewise, there is no dispute that Dey has sole ANDA “first filer” status for the fourth commercial presentation of Xopenex®, 1.25 mg/0.5 mL, referred to as the “concentrate.”

⁴ “Exh. ___” refers to exhibits attached to the accompanying February 29, 2008 Declaration of Preston K. Ratliff II.

3.

even been set, making the prospect of a final judgment in August 2008 (or indeed anytime prior to February 2009) exceedingly unlikely.

Dey's argument that consolidation will delay market entry of the three most commercially significant product strengths that it seeks to sell also is incorrect. As Sepracor explained in its opening brief, Breath's sole ANDA first-filer exclusivity prevents Dey from marketing until six months (180 days) after Breath first markets its products. [D.I. 254 at 3-4.]⁵ Dey suggests that a decision by this Court could create a forfeiture of Breath's first-filer exclusivity and therefore allow Dey to market its products sooner. [D.I. 255 at 8-9.] This is wrong. As Dey admits in its brief (at page 9), Dey could only cause a forfeiture of Breath's first-filer exclusivity if Dey received a decision of patent invalidity or non-infringement with respect to each patent that Breath has challenged.⁶ This is impossible for Dey because the Dey case does not involve Sepracor's '289 patent, which is at issue in the Breath case.

Further, although Dey devotes an entire section of its brief to emphasizing that this is a Hatch-Waxman case (D.I. 255 at 6-7), it fails to refute the large body of Hatch-Waxman case law Sepracor cites where cases such as these have been consolidated. [D.I. 254 at 5-6.]

⁵ Unless specified otherwise, all "D.I." references herein refer to the document index number in the Dey case, C.A. No. 06-113-JJF.

⁶ The Hatch-Waxman Act provides Breath with 180 days of exclusivity by specifying that Dey's ANDA (and Barr's ANDA) "shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant," *i.e.*, Breath. 21 U.S.C. § 355(j)(5)(B)(iv)(I). Breath's 180 day exclusivity can only be forfeited under conditions specified in the statute, most notably if "*as to each of the patents* with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), ... a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed." 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) (emphasis added). Breath submitted paragraph IV certifications on the five patents at issue in the Dey and Barr cases as well as Sepracor's '289 patent.

4.

Instead, Dey relies on four distinguishable cases that involve neither the Hatch-Waxman Act, nor are even patent cases. [D.I. 255 at 10.] For example, in *La Chemise Lacoste v. The Alligator Co., Inc.*, 60 F.R.D. 164 (D. Del. 1973), the court held that consolidation was not appropriate because the first case had been pending for over three years and was ready for trial while the second case had only recently been filed. Further, the first case involved seven distinct issues of law and fact while the second case involved three separate and distinct issues. *Id.* at 175. Unlike *La Chemise Lacoste*, the Dey and Barr cases involve similar infringement issues and identical validity and enforceability issues, and the timing of the cases is much closer.

In *Mills v. Beech Aircraft Corp., Inc.*, 886 F.2d 758 (5th Cir. 1989), the Fifth Circuit upheld a district court's denial of consolidation because consolidation was not requested until eight months after the final pretrial order was filed in the first action. *Id.* at 762. Here, no final pretrial preparations have been scheduled.

In *Lewis v. Four B Corp.*, 347 F. Supp. 2d 1017 (D. Kan. 2004), the court declined to consolidate because the two cases only shared one common issue of law or fact. *Id.* at 1020. The first case involved only an allegation of race discrimination taking place in 2003 while the later case involved allegations of race, color, and sex discrimination taking place in 2004. *Id.* at 1019.

In *St. Bernard Gen. Hosp., Inc. v. Hosp. Service Assoc. of New Orleans, Inc.*, 712 F.2d 978 (5th Cir. 1983), the Fifth Circuit upheld a district court's denial of consolidation because the first case had been pending for *over a decade* and was ready for trial while the second case was still in the discovery phase. *Id.* at 990.

Dey also argues that Judge Thyng previously considered and rejected consolidation of the Dey and Barr cases. [D.I. 255 at 12.] The proposal before Judge Thyng,

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however, related only to consolidating the Markman proceedings in these cases, and not consolidating them for all purposes as requested here. [D.I. 207 at 17:18 – 18:1.]

Finally, Dey argues that Sepracor somehow delayed expert depositions because Sepracor took its first deposition of a Dey expert on February 22, 2008. Dey's argument makes no sense. As Sepracor explained to Dey in January and again in early February, expert depositions in the Breath case overlap with the current expert deposition period in the Dey case. [Exhs. 2-3.] In fact, *both* parties proposed dates in early February for expert depositions, and as is often the case, *both* parties were unable to take the depositions on these early dates. Sepracor took its first deposition of a Dey expert on February 22, 2008 and Dey took its first deposition of a Sepracor expert nearly a week later, on February 28, 2008. Again, Dey's claim that Sepracor has delayed makes no sense where, as explained above, the progress of this case is irrelevant to the market entry of Dey, or any other generic for that matter.

6.

CONCLUSION

For the foregoing reasons and those set forth in Sepracor's opening brief, Sepracor respectfully requests that the Court consolidate the Barr and Dey cases for all purposes.

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February 29, 2008

CERTIFICATE OF SERVICE

I, hereby certify that on February 29, 2008, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

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